

REMARKS

Claims 224-292 are pending. By this Amendment, claim 225 is amended.

Reconsideration in view of the above amendment and following remarks is respectfully requested.

I. The Specification Satisfies All Formal Requirements

The Office Action objects to the specification for introducing new matter into the disclosure. Applicants respectfully disagree with the Examiner's position.

With respect to the insertion of "and/or fluorescent tagged co-polymer" on pages 6, 15, 29 and 30, this disclosure was provided in at least claim 199 of the application as originally filed.

With respect to the insertion of "flushing or perfusion may reduce or stop catabolic changes, such as free radical activity, apoptic enzymatic degradation and vascular permeability", these features are disclosed in at least Figure 16 and also in claim 31 of the application as originally filed.

With respect to the insertion of "a medical fluid under normothermic conditions may also include an oxygen carrier, a free radical scavenger, a pituitary growth factor extract and/or cell culture media", this disclosure was provided in at least claim 162 of the application as originally filed.

With respect to the insertion that the normothermic temperatures are from about "10 to about 24°C", this feature is clearly disclosed on page 23. Specifically, the normothermic temperatures are from about 12 to about 24°C, but higher or lower temperatures can be used, as desired and/or necessary.

**II. Claims 224-267 Satisfy the Requirements
of 35 U.S.C. §112, First Paragraph**

Claims 224-267 are rejected under 35 U.S.C. §112, first paragraph. Applicants respectfully disagree with this rejection.

With respect to claim 224 and the recitation of "energy levels in the organ", these features can be found, for example, on page 21, lines 18-23 disclosing that the mitochondria are provided with sufficient amounts of oxygen so that pre-ischemia levels of reserve high energy nucleotide levels in the organ are maintained and/or restored.

Claim 224, as presently presented, should not necessarily be read in light of the original claim language of the application as filed. The first medical fluid not requiring oxygen is fully supported by the specification. For example, page 9, lines 28-30 disclose the first perfusion solution may contain at least one oxygen carrier, may be oxygenated and/or may be selected from the group consisting of cross-length hemoglobin and stabilized red blood cells. By disclosing that the first perfusion solution may contain at least one oxygen carrier and that the solution may be oxygenated is merely optional, the specification makes clear to one of ordinary skill in the art that the first perfusion solution does not necessarily require oxygen.

Claim 225 as amended recites that the first temperature is "up to about 24°C". Withdrawal of the rejection of claim 225 is respectfully requested.

Claim 227 recites "at least about 15°C". This disclosure was provided in at least claim 37 of the application as originally filed.

Additionally, claim 230 recites "about 20°C to about 38°C". The temperature range as disclosed on page 26 is a medical fluid maintained preferably within the range of approximately 10°C to 38°C. Accordingly, the term approximately applies to both ends of the recited range. That is, the fluid is maintained within the range of approximately 10°C to

approximately 38°C. Accordingly "about 38°C" is fully supported by the disclosure in the specification. Similarly, with respect to claim 232, page 30 of the application discloses that in the hypothermic mode, an organ is perfused with a cooled medical fluid, preferably within a range of approximately 1°C to 15°C.

With respect to "viability marker", this disclosure was provided in at least claim 146 of the application as originally filed.

With respect to the recitation in claims 261-264 of "at most 15°C" and "at most 10°C" of the portable container, these features are disclosed at least at claims 40, 43, 182 and 184 of the original claims as filed with the application.

Withdrawal of the rejection of claims 224-267 under 35 U.S.C. §112, first paragraph is respectfully requested.

**III. Claims 228 and 251-253 Satisfy the Requirements
of 35 U.S.C. §112, Second Paragraph**

Claims 228 and 251-253 are rejected under 35 U.S.C. §112, second paragraph as indefinite. Applicants respectfully disagree with the Examiner's assertions.

With respect to "about room temperature", it is well understood by one of ordinary skill in the art and is not indefinite. Further, the discussion of "what approximately room temperature" is discussed on page 26, line 29. For example, "room temperature 22-23°C".

With respect to "hypothermic temperature", this term is used throughout the specification and is well defined with respect to what are the metes and bounds of the term "hypothermic" and this term is within the level of one of ordinary skill in the art. For example, on page 30 of the specification, in the hypothermic mode, an organ is perfused with a cooled medical fluid, preferably at a temperature within a range of approximately 1°C to 15°C, more preferably 4 °C to 10 °C, most preferably around 10 °C.

With respect to claim 256, it is well within the level of one of ordinary skill in the art to perfuse an organ after it has been transplanted. For example, as disclosed on page 23, lines 10-11, after transplant, the organ may be perfused at normothermic temperatures in vivo or allowed to warm up from the circulation of the donee.

Accordingly, withdrawal of the rejection of claims 228 and 251-253 under 35 U.S.C. §112, second paragraph is respectfully requested.

IV. The Claims Define Patentable Subject Matter

Claims 224-245, 248-252 and 258-266 are rejected under 35 U.S.C. 102(b) as anticipated by WO 88/05261 to Owen; claims 246 and 247 are rejected under 35 U.S.C. §103(a) as unpatentable over Owen in view of WO 96/29864; claims 253 and 254 are rejected under 35 U.S.C. §103(a) as unpatentable over Owen in view of Chambers et al.; claims 255 is rejected under 35 U.S.C. §103(a) as unpatentable over Owen; claim 257 is rejected under 35 U.S.C. §103(a) as unpatentable over Owen in view of Ingawall or WO 97/43899; claims 259-266 are rejected under 35 U.S.C. §103(a) as unpatentable over Owen in view of U.S. Patent No. 5,586,438 to Fahy; and claim 267 is rejected under 35 U.S.C. §103(a) as unpatentable over Owen and Fahy, and further in view of Tanner et al. These rejections are respectfully traversed.

None of the applied art teaches, discloses or even suggests perfusing at least one organ with a first medical fluid at a first temperature to at least one of maintain and restore pre-ischemia or pre-hypoxia energy levels in the organ, as claimed in claim 224.

Instead, Owen is directed to an invention which relates particularly to a total organ perfusion system that allows a donor organ to be maintained extra corporeally for an extended period of time. Further, Owen is concerned with maintaining the organ tissue by maintaining a correct electrolyte balance on either side of the cell membrane with a minimum of ATP usage by the organ or tissue. Additionally, Owen discloses that the organs perfused with the

methods of Owens, can be changed between normothermic and hypothermic conditions without tissue degradation (ischemia). As such, Owen does not teach or disclose or even suggest perfusing an organ to at least one of maintain and restore pre-ischemia or pre-hypoxia energy levels in the organ. That is, Owen is concerned with controlling ATP usage during perfusion, not maintaining or restoring the pre-ischemia or pre-hypoxia levels.

None of the other cited art makes up for the deficiencies of Owen discussed above.

The present application perfuses the organ with medical fluid so that pre-ischemia levels of reserve high energy nuclear type are maintained and/or restored. This feature is not taught, disclosed or even suggested, nor has the Examiner directed the Applicants' attention to a particular disclosure in Owen for the above discussed features of the present application.

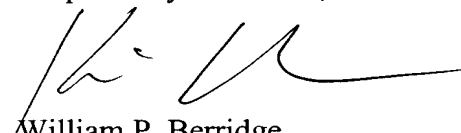
Accordingly, withdrawal of the rejection of claims 224-267 under 35 U.S.C. §102 and §103 is respectfully requested.

V. Conclusion

In view of the foregoing, it is respectfully submitted that this application is in condition for allowance. Favorable reconsideration and prompt allowance are earnestly solicited.

Should the Examiner believe that anything further would be desirable in order to place this application in even better condition for allowance, the Examiner is invited to contact the undersigned at the telephone number listed below.

Respectfully submitted,



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Attachment:
Petition for Extension of Time

Date: September 22, 2003

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